DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3641. Misbranding of Gattis worm oil. U. S. v. 9 Cases * * *. (F. D. C. No. 29057. Sample No. 82206–K.)

LIBEL FILED: On or about April 13, 1950, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about March 10, 1950, by the Gattis Chemical Co., from Nashville, Tenn.

PRODUCT: 9 cases, each containing 12 1-ounce bottles, of *Gattis worm oil* at Williamson, W. Va.

LABEL, IN PART: "Gattis' Worm Oil Each Fluid Ounce Contains: 22 Mins. Oil Worm Seed, 12 Mins. Chloroform, 421 Mins. Castor Oil, Turpentine, Combined with Aromatics. Directions: Children 2 to 5 years old, one-half teaspoonful; 5 to 10 years old, one teaspoonful. Adults, one and a half teaspoonfuls. One dose morning and night; (May be given for 2 or 3 days if necessary.)."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: May 8, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3642. Misbranding of pentobarbital sodium capsules, Seconal Sodium capsules, sulfadiazine tablets, and racemic amphetamine sulfate (Benzedrine Sulfate) tablets. U. S. v. Edmond V. Bragard (Bragard Pharmacy). Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 31275. Sample Nos. 79358–K, 79361–K, 79369–K, 79373–K, 79376–K, 79395–K, 79399–K, 80426–K, 80427–K, 80447–K, 80574–K, 80578–K, 80583–K, 80587–K.)

INFORMATION FILED: December 10, 1951, District of Rhode Island, against Edmond V. Bragard, trading as Bragard Pharmacy, Woonsocket, R. I.

INTERSTATE SHIPMENT: From the States of Massachusetts, Indiana, and Pennsylvania, into the State of Rhode Island, of quantities of *pentobarbital sodium capsules, Second Sodium capsules, sulfadiazine tablets,* and *racemic amphetamine sulfate (Benzedrine Sulfate) tablets.*

ALLEGED VIOLATION: On or about September 2, 1949, and August 8, 24, and 31, September 18, October 17, 23, 24, 30, and 31, and November 3, 8, and 9, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged *pentobarbital sodium capsules, Seconal Sodium capsules,* and *racemic amphetamine sulfate (Benzedrine Sulfate) tablets* failed to bear adequate directions for use;

and Section 502 (e) (1), the labels of the repackaged *racemic amphetamine sulfate tablets* and the *sulfadiazine tablets* failed to bear the common or usual name of the drug.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* and the *pentobarbital sodium capsules* contained derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels on the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear adequate warnings against use in those pathological conditions where the use of the drug may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 18, 1951. A plea of guilty having been entered, the court placed the defendant on probation for 2 years.

3643. Misbranding of pentobarbital sodium capsules, Dexedrine Sulfate tablets, and sulfadiazine tablets. U. S. v. Bond Drug Store, Harold G. Griffin, and Robert V. West. Pleas of guilty. Fine of $135, plus costs, against individuals jointly. No fine imposed against partnership. (F. D. C. No. 30567. Sample Nos. 76956-K, 76964-K, 76977-K, 76978-K, 77147-K, 77772-K, 78216-K, 78218-K.)

INFORMATION FILED: April 26, 1951, Western District of Missouri, against the Bond Drug Store, a partnership, Lebanon, Mo., and Harold G. Griffin, a partner in the partnership, and Robert V. West, a pharmacist for the partnership.

INTERSTATE SHIPMENT: From the States of Illinois, Indiana, and Pennsylvania, into the State of Missouri, of quantities of *pentobarbital sodium capsules*, *Dexedrine Sulfate tablets*, and *sulfadiazine tablets*.

ALLEGED VIOLATION: On or about May 21, June 12 and 17, and July 5, 6, and 12, 1950, while the drugs were being held for sale at the Bond Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

The Bond Drug Store and Harold G. Griffin were charged with causing the acts of repacking and sale of the drugs involved in each of the 8 counts of the information, and, in addition, Robert V. West was charged in 2 of the counts with causing such acts to be done in connection with the drug involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further, misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* and the *sulfadiazine tablets* failed to bear labels containing the common